KCE TRIALS PROGRAMME
STANDARD OPERATING PROCEDURE

Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

TITLE: CONFIDENTIALITY AND POTENTIAL CONFLICT OF INTEREST OF REVIEWERS INVOLVED IN THE ASSESSMENT OF PROPOSALS.		
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1 PURPOSE

This procedure describes how confidentiality is assured and how potential conflicts of interest are identified and managed in relation to the KCE Trials programme.

2 SCOPE

This procedure applies to all appointed reviewers (advisory board members and other experts) who provide advice or input related to assessment of proposals in the KCE Trials programme and more specifically to funding decisions

3 DEFINITIONS/ACRONYMS

PG: Prioritization Group

TB: Trials Board

COI: Conflict of Interest

4 PROCEDURES

4.1 Confidentiality undertaking

Prior to participation in KCE Trials selection and funding activities, all individuals participating in the KCE Trials panels, Trials Board (TB), Prioritisation Group (PG) and external reviewers must sign an undertaking to treat all information that they receive related to KCE Trials programme confidentially.

4.2 Potential conflict of interest

KCE Trials takes care to ensure that its scientific experts and advisory group members do not have any financial or other interests that could affect their impartiality.

KCE Trials takes a proactive approach to identifying cases where the potential involvement of an expert in its activities needs to be restricted or excluded due to interests in the healthcare industry, and to searching for alternative experts where necessary.

This procedure reflects a balanced approach to handling Conflict of interest (COI)s that aims to effectively restrict the involvement of experts with possible COI in KCE Trials work while maintaining its ability to access the best available expertise.

Experts can only be involved in KCE Trials selection and funding activities if they declare their project-specific COIs in the SmartSimple grant management system before accessing any project-related documents. Moreover all proposed members for the TB and the PG need to have signed a declaration of longstanding interests form before they start activities related to KCE Trials.

4.3 Declaration of long standing interests

When invited to join an advisory group (TB, PG), members must declare any longstanding interests. Declaration of a longstanding interest does not necessary mean a COI. Members must inform trials@KCE.fgov.be of any change to their longstanding interests, if and as they occur, during their mandate.

Every 4 years, the advisory/committee members are asked to renew the longstanding interests form.

The most recent declaration of long standing interests of all active advisory group members will be saved and documented in in the SmartSimple grant management system.

4.4 Declaration of potential conflict of interests in relation to specific activities, meetings and proposals

4.4.1 Requirements for Chairs and members in a lead role

Requirements for Board and meeting Chairs and members in a lead role, e.g. rapporteurs, are stricter than requirements for the other committee members. If there is any potential conflict the Chair will hand over to another member of the KCE Trials Team for the discussion of the project. Additional care is taken when individuals are approached for a lead role to ensure identification of and transparency related to any potential conflict.

4.4.2 Additional requirements for individuals who are potential applicants

All members of advisory boards who are potential applicants should be members of only one advisory board (for example they cannot be members of both the PG and TB). This does not apply to people who will never be an applicant (e.g. NIHDI, cabinet,). An exception can be made for the Panel if no other available reviewer with the required expertise can be identified.

When a PG member is a lead applicant in a specific call, they must be replaced for their membership of the PG for the duration of the call selection process for which they submitted a proposal, by another representative e.g. another university member or KCE Board member (if representative). If their proposal is funded, they should also be replaced for the duration of the trial. When a PG member is a co-applicant in a specific call, they can continue to be a member of the PG however they will need to leave the room during discussion of the project for which they are a co-applicant.

When a TB member is lead applicant or co-applicant, they will need leave the room during discussion of the project for which they are a (co-)applicant.

A lead applicant or co-applicant can never be Panel member for the call in which they have applied.

4.4.3 Associated with meeting

A probity report (with both longstanding interests and per proposal) to be reviewed will be prepared for all meetings and provided to all members of the meeting. It will be supplemented with any additional information that comes to light before, during or after the meeting. The Chair will decide how potentially conflicting interests are managed during the meeting, usually by having members leave the room during the discussion of specific proposals for which they have a conflict (see 4.6 for detailed information).

A record will be kept of which members leave the room for the review of which projects and any associated withdrawal from voting. This probity report will be signed afterwards by the Chair (or another member of the KCE Trials Team that was present during the meeting) and shared with the members of the advisory group.

4.4.4 At any other time

At any time if individuals involved in KCE Trials activities become aware of an interest that could be perceived to lead to a COI or any interests that could potentially cause embarrassment or damage the credibility of the individual or the KCE Trials programme if they subsequently come to light in relation to the decision making of KCE Trials, they should notify the Board or meeting Chair or KCE Trials team immediately.

4.5 External and or international reviewers and experts

External and/or international reviewers and experts must sign a confidentiality undertaking and COI form prior to being provided with documentation to review. If potentially conflicting interests are declared, the Board or meeting

Chair will decide whether the individual may be asked to review the proposal or not and if so what level of transparency related to any potential conflict is required e.g. to notify members of the Board or meeting that the comments come from someone in a leading role in a similar academic study.

4.6 Adjudication of potential conflict of interests

COIs are judged on a proposal by proposal basis. The KCE Trials team performs the initial review but all decisions are approved by or taken by the Board or meeting Chair.

Members with a COI shall leave the meeting for the discussion of that item and will thus not participate in any voting on the particular item. When all proposals are discussed collectively (e.g. when the ranking of the proposals is shown), members with a COI shall refrain from any comment on the proposal for which there is a COI. The degree of COI is measured as follows:

- The Chair shall be deemed to have a COI if any of the applicants are from the same institution or there is a personal relationship with any of the applicants.
- Other members of the board shall be deemed to have a COI if:
    - the (co-) applicant is from the same department, former department (<5y ago) or equivalent.
    - the (co-) applicant is a close friend or family member
    - the member's department (or equivalent) participates in the trial
    - the member and the (co-) applicant closely collaborate(d) in a research project (e.g. joint publication <5y ago)
- If the applicant is from the same institution as a board member, a COI will not necessarily arise and this can be left to the discretion of the board member and the Chair. Should the Chair decide that a COI does exist, that board member shall leave the meeting for the duration of the relevant item. Even if it is decided that no COI exists, the board member will preferably not be assigned as a rapporteur.
- COIs should be declared at the earliest opportunity before the board meeting, either to the KCE Trials team or to the Chair.

4.7 Publication of interests

KCE Trials reserves the right to publish all declaration of interest information on its website. Summarised information from the table of declared interests and how they were handled in the decision making may be made public with the minutes of any meeting.

5 REFERENCES

Probity report
Confidentiality undertaking
KCET_WI_SE_003_Meetings and Reviews

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